K133339

MAR 0 4 2014

Zimmer Dental 1900
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PRE-MARKET NOTIFICATION 510(K)
Traditional 510(k):
Zimmer Dental *Tapered Screw-Vent*® T Implant, HA Coated
Zimmer Dental *Tapered Screw-Vent*® M Implant, HA Coated

510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4366
Contact:	Julie Lamothe Corman
Date Prepared:	January 28, 2014

2. Device Name:

Trade Name:	Zimmer Dental *Tapered Screw Vent*® T Implant, HA Coated Zimmer Dental *Tapered Screw Vent*® M Implant, HA Coated
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

3. Predicate Device(s):

Predicate Device No. 1	
Trade Name:	Zimmer Dental *Tapered Screw Vent*® Implant, HA Coated
510(k):	K013227, K061410
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form
Predicate Device No. 2	
Trade Name:	Zimmer Dental *Tapered Screw Vent*® T Implant Zimmer Dental *Tapered Screw Vent*® M Implant
510(k):	K101977, K111889
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

4. Device Description:

The Zimmer Dental *Tapered Screw-Vent*® T Implant, HA Coated and Zimmer Dental *Tapered Screw-Vent*® M Implant, HA Coated are a self-tapping, screw type endosseous dental implant designed for bone level placement and can be used in a single or two stage protocol. The implant is composed of titanium alloy with hydroxylapatite (HA) coating, and has a tapered body with an external triple lead thread design. Identical to predicate #1, the new device has the same implant to abutment internal hex friction-fit connection. The new device will have coronal microgrooves that extend to the collar within 0.64mm of the top of the implant identical to predicate #2.

The new implant will be offered in two surface finish configurations at the coronal end: full MTX texturing to the top of the implant and partial MTX texturing to 0.5mm from the top of the implant leaving a machined collar. Both coronal configurations are identical to the currently marketed predicate #2 device (K101977, K111889).

The Zimmer Dental *Tapered Screw-Vent*® T Implant, HA Coated and Zimmer Dental *Tapered Screw-Vent*® M Implant, HA Coated family is composed of tapered implants with a choice of diameters and lengths. Both implant configurations, machined and fully textured collar, will be available in diameters of 3.7mm, 4.1mm, 4.7mm, and 6.0mm and in five lengths: 8, 10, 11.5, 13, and 16mm. The implant/abutment interface platform diameter will be offered in sizes of 3.5mm, 4.5mm, or 5.7mm depending on the outside implant thread diameter. The drilling sequences and drills that will be utilized to place the new device are pre-existing sequences and drills that are listed in the previous 510(k) K011028.

5. Indications for Use:

The Zimmer Dental *Tapered Screw-Vent*® T Implant, HA Coated and Zimmer Dental *Tapered Screw-Vent*® M Implant, HA Coated are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional or delayed healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

6. Device Comparison:

The new device is equivalent to Predicate #1: *Tapered Screw-Vent*® family implants (K061410) in implant/abutment connection, implant body design, materials, indication, surface coating, implant sizes and manufacturing

processes. The only difference in the new design is the coronal section of the device, which is identical to Predicate #2: *Tapered Screw-Vent*® T Implant and *Tapered Screw-Vent*® M Implant (K101977, K111889); machined or MTX textured.

The new implant line will be offered in identical length and diameters to predicate #1.

7. Technological Characteristics

Feature	**New Device:** Zimmer Dental *Tapered Screw-Vent*® T Implant, HA Coated and Zimmer Dental *Tapered Screw-Vent*® M Implant, HA Coated	**Predicate Device 1:** Zimmer Dental *Tapered Screw-Vent*® Implant, HA Coated Surface	**Predicate Device 2:** Zimmer Dental *Tapered Screw-Vent*® T Implant and Zimmer Dental *Tapered Screw-Vent*® M Implant
Implant Interface	Internal Hex	Internal Hex	Internal Hex
Implant Lengths	8mm,10mm,11.5mm, 13mm, 16mm	8.0mm,10mm,11.5mm, 13mm, 16mm	8mm,10mm,11.5mm, 13mm, 16mm
Implant Diameters	3.7mm, 4.1mm, 4.7mm, 6.0mm	3.7mm, 4.1mm, 4.7mm, 6.0mm	3.7mm, 4.1mm, 4.7mm, 6.0mm
Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V
Surface Body Characteristics	HA Coating	HA Coating	MTX Surface

8. Non-Clinical Testing:

Non-clinical test data was used to support the decision of substantial equivalence. Non-clinical testing consisted of performance of fatigue and compression testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments. The testing indicates that the device is strong enough to withstand the anticipated forces and demonstrated improvements over the predicate device.

Additionally, Zimmer Dental implant systems were evaluated for interactions with magnetic fields during Magnetic Resonance Imaging (MRI) in accordance with the FDA Guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment.

9. Clinical Testing:

No clinical testing was performed. Non-clinical testing was used to support the decision of substantial equivalence.

10. Conclusion:

Based on our analysis, the device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2014

Zimmer Dental Incorporated
Ms. Julie Lamothe Corman
Regulatory Affairs Manager
1900 Aston Avenue
Carlsbad, CA 92008

Re: K133339
Trade/Device Name: Zimmer Dental Tapered Screw Vent® T Implant, HA Coated
Zimmer Dental Tapered Screw Vent® M Implant, HA Coated
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 28, 2014
Received: January 30, 2014

Dear Ms. Corman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133339

Device Name: Zimmer Dental *Tapered Screw-Vent*® T Implant, HA Coated
Zimmer Dental *Tapered Screw-Vent*® M Implant, HA Coated

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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